ASX ANNOUNCEMENT

19 November 2026

Registrational Phase III AMPLIFY trial: Follow-up assessments completed for all participants

Clarity Pharmaceuticals (ASX: CU6) ("Clarity" or "Company"), a clinical-stage radiopharmaceutical company with a mission to develop next-generation products that improve treatment outcomes for patients with cancer, is pleased to announce that the last patient has completed their final follow-up assessments in the Phase III diagnostic ^{64}Cu-SAR-bisPSMA trial, AMPLIFY (NCT06970847)[1].

AMPLIFY (^{64}Cu-SAR-bisPSMA Positron Emission Tomography: A Phase 3 Study of Participants with Biochemical Recurrence of Prostate Cancer) is a non-randomised, single-arm, open-label, multi-centre, diagnostic clinical trial of ^{64}Cu-SAR-bisPSMA positron emission tomography (PET) in participants with rising or detectable prostate-specific antigen (PSA) after initial definitive treatment at clinical sites across the US and Australia.

The aim of this registrational study is to investigate the diagnostic ability of ^{64}Cu-SAR-bisPSMA PET/computed tomography (CT) to detect recurrence of prostate cancer in men with PSA levels above 0.2 ng/mL. The study co-primary endpoints are participant-level correct detection rate (CDR) and region-level positive predictive value (PPV) assessed independently for same-day and next-day imaging (1-4 hours and approximately 24 hours post-administration, respectively). The AMPLIFY study also has a number of exploratory endpoints, such as direct comparisons of ^{64}Cu-SAR-bisPSMA to standard-of-care (SOC) prostate-specific membrane antigen (PSMA) PET agents.

AMPLIFY commenced in May 2025, seeking to enrol approximately 220 participants, and the first trial participant was imaged in the same month at XCancer with Dr Luke Nordquist (Omaha, NE). The target number of participants in the AMPLIFY study was achieved in March 2026, with the rapid pace of recruitment underscoring the substantial unmet need for improved diagnostic imaging in the biochemical recurrence (BCR) setting.

Most recently, Clarity was granted Breakthrough Therapy designation for ^{64}Cu-SAR-bisPSMA in BCR of prostate cancer by the United States (US) Food and Drug Administration (FDA)[2]. Breakthrough Therapy designation is a process designed to expedite the development and review of products that are intended to treat a serious condition, and preliminary clinical evidence indicates that the agent may demonstrate substantial improvement over available products on a clinically significant endpoint(s)[3]. The Breakthrough Therapy designation was supported by the Phase I/IIa COBRA[4] and Phase II Co-PSMA[5] trials as well as real-world evidence[6]. This evidence has collectively demonstrated enhanced imaging capabilities of ^{64}Cu-SAR-bisPSMA over SOC PSMA PET in patients with BCR of prostate cancer[4-6].

The Breakthrough Therapy designation represents the latest in a series of US FDA recognitions for the SAR-bisPSMA platform. Prior to receiving Breakthrough Therapy designation, ^{64}Cu-SAR-bisPSMA had already received two Fast Track designations spanning PET imaging in patients with suspected metastasis who are candidates for initial definitive therapy[7] and those with BCR following definitive therapy[8], with the latter supported primarily by data from the COBRA study[4]. This regulatory recognition extends across the broader SAR-bisPSMA program, with ^{67}Cu-SAR-bisPSMA also receiving Fast Track designation for the treatment of PSMA-positive metastatic castration-resistant prostate cancer (mCRPC) following androgen receptor pathway inhibitor [ARPI] and androgen deprivation therapy [ADT])[9].

^{64}Cu-SAR-bisPSMA is also currently being evaluated in another registrational Phase III trial, CLARIFY (NCT06056830)[10], which is expected to complete last participant assessments in calendar year (CY) 2026. Building on the Phase I PROPELLER[11] study, the objective of CLARIFY is to assess the diagnostic performance of ^{64}Cu-SAR-bisPSMA PET across same-day and next-day imaging in detecting prostate cancer within the pelvic lymph nodes in patients who are scheduled to undergo radical prostatectomy and pelvic lymph node dissection.

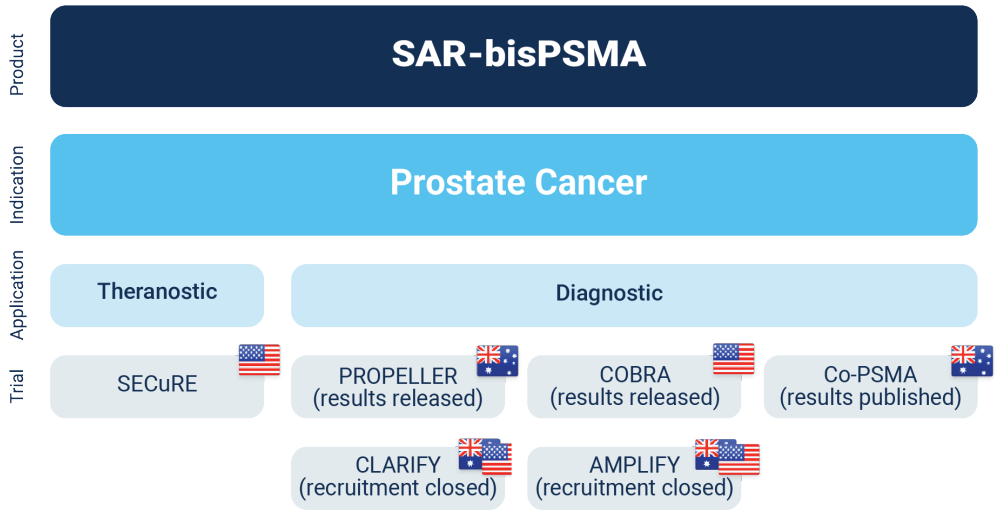
Topline data from the AMPLIFY and CLARIFY trials are anticipated to be released in the first half of CY2027. As pivotal trials, the final study results are intended to provide sufficient evidence to support applications to the US FDA for approval of ^{64}Cu-SAR-bisPSMA as a new diagnostic imaging agent in BCR (AMPLIFY) and in prostate cancer patients prior to undergoing definitive therapy (CLARIFY).

Dr Alan Taylor, Executive Chairperson of Clarity Pharmaceuticals, commented, "The completion of all patients' follow-ups is an important step as our team and collaborators continue to work with all participating sites on the entry of the final data. This will be followed by analysis and release of topline results, expected in the first half of CY2027. We look forward to commencing our module submissions for our New Drug Application (NDA) with the US FDA under their rolling review process as part of the Breakthrough Therapy designation.

"What we find extraordinary about our SAR-bisPSMA BCR program is that, to our knowledge, this is the first time in the history of the US FDA Breakthrough Therapy designation program that an Australian company (Clarity) has received the designation for a product that was invented and developed, from the lab to the clinic, in Australia. Clarity is also the first company globally to receive Breakthrough Therapy designation for a PSMA PET imaging agent. Furthermore, of the more than 1,300 applications the US FDA has received for Breakthrough Therapy designation across all therapeutic areas, fewer than half have been awarded[12], and we believe that only a single-digit number of diagnostics have received this designation. This is an incredible accomplishment, and we are proud to see this phenomenal Australian science story unfold.

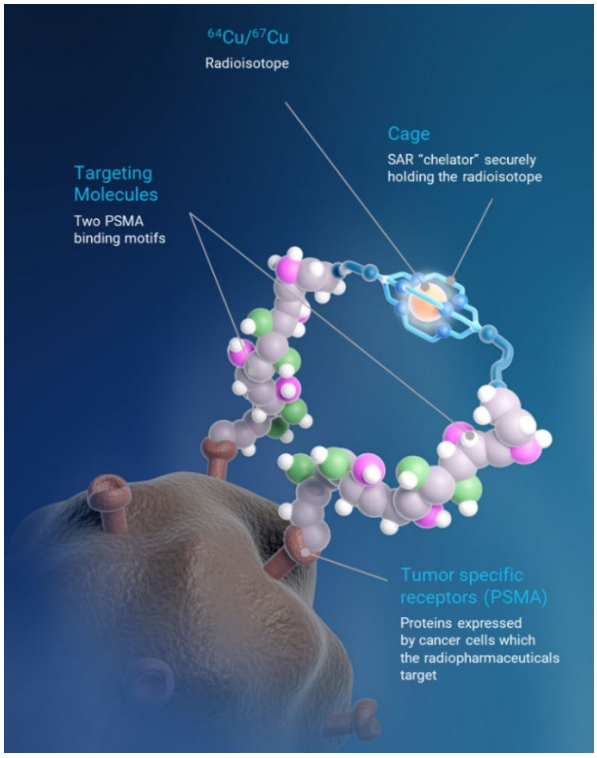
"The Breakthrough Therapy and Fast Track designations awarded to ^{64}Cu-SAR-bisPSMA further underscore the unmet need and help expedite the development of our optimised product in BCR of prostate cancer, with the goal of bringing it to patients who need it most, as fast as possible. With a next-generation product, we believe we are well positioned to address this growing market opportunity, predicted to exceed US$3Bn by 2029, while better serving patients and their clinicians in the pursuit of our ultimate goal to improve treatment outcomes for people with cancer."

Overview of Clarity's SAR-bisPSMA clinical trial program



About SAR-bisPSMA

SAR-bisPSMA derives its name from the word "bis", which reflects a novel approach of connecting two PSMA-targeting agents to Clarity's proprietary sarcophagine (SAR) technology that securely holds copper isotopes inside a cage-like structure, called a chelator. Unlike other commercially available chelators, the SAR technology prevents copper leakage into the body. SAR-bisPSMA is a Targeted Copper Theranostic (TCT) that can be used with isotopes of copper-64 (Cu-64 or ^{64}Cu) for imaging and copper-67 (Cu-67 or ^{67}Cu) for therapy.



Disclaimer

^{64}Cu-SAR-bisPSMA and ^{67}Cu-SAR-bisPSMA are unregistered products. Their safety and efficacy have not been assessed by health authorities such as the US FDA or the Therapeutic Goods Administration (TGA). There is no guarantee that these products will become commercially available.

About Prostate Cancer

Prostate cancer is the second most common cancer diagnosed in men globally and the fifth leading cause of cancer death in men worldwide[13]. Prostate cancer is the second-leading cause of cancer death in American men. The American Cancer Society estimates there will be about 333,830 new cases of prostate cancer in the US in 2026 and around 36,320 deaths from the disease[14].

About Clarity Pharmaceuticals

Clarity is a clinical stage radiopharmaceutical company focused on the treatment of serious diseases. The Company is a leader in innovative radiopharmaceuticals, developing Targeted Copper Theranostics based on its SAR Technology Platform for the treatment of cancers.

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This announcement has been authorised for release by the Executive Chairperson.